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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

TAMMY BEAL, Individually and on Behalf of
All Others Similarly Situated,

Plaintiff,

v.

GRITSTONE BIO, INC., ANDREW R. ALLEN,
and VASSILIKI ECONOMIDES,

Defendants.

Case No.

CLASS ACTION

COMPLAINT FOR VIOLATIONS OF THE
FEDERAL SECURITIES LAWS

DEMAND FOR JURY TRIAL

Plaintiff Tammy Beal (“Plaintiff”), individually and on behalf of all others similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the Defendants’ public documents, conference calls and announcements made by Defendants, United States (“U.S.”) Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Gritstone bio, Inc. (“Gritstone” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff

believes that substantial, additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired Gritstone securities between March 9, 2023 and February 29, 2024, both dates inclusive (the “Class Period”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. Gritstone, a clinical-stage biotechnology company, engages in developing vaccine-based immunotherapy candidates against cancer and infectious diseases.

3. In September 2023, Gritstone entered into a contract with the Biomedical Advanced Research and Development Authority (“BARDA”) to run a 10,000 participant, randomized Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of its COVID-19 vaccine candidate (a samRNA vaccine candidate) with an approved COVID-19 vaccine (the “Phase 2b CORAL Study” or the “Study”). In a press release announcing the Phase 2b CORAL Study, the Company stated that the contract “provides strong validation of [its] innovative vaccine platform in infectious diseases,” that execution of the study would be fully funded by BARDA, and that the Study would be expected to launch in the first quarter of 2024.

4. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company’s business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company would be unable to launch the Phase 2b CORAL Study in the timeframe it had

1 represented to investors; (ii) the foregoing would impair Gritstone’s ability to obtain external
2 funding in connection with the Study, thereby negatively affecting Gritstone’s ability to maintain
3 its balance sheet and cash position; (iii) accordingly, Gritstone overstated its ability to
4 successfully develop and commercialize its products; (iv) as a result, the Company’s public
5 statements were materially false and misleading at all relevant times.
6

7 5. On February 12, 2024, Gritstone issued a press release announcing that the
8 Company was delaying the launch of the Study until Fall 2024 to purportedly “allow use of fully
9 GMP-grade raw materials in the vaccine, which is expected to increase the regulatory utility of
10 the trial.”

11 6. Then, on February 29, 2024, Gritstone issued a press release “announc[ing] an
12 approximately **40% reduction of its workforce**”, stating that “[t]he move comes following the
13 recently announced delay of the proposed CORAL Phase 2b study, which resulted in Gritstone
14 not receiving external funding it previously anticipated beginning in 1Q 2024, associated with the
15 initiation of the study.”¹
16

17 7. On this news, Gritstone’s stock price fell \$0.78 per share, or 27.86%, to close at
18 \$2.02 per share on March 1, 2024.

19 8. As a result of Defendants’ wrongful acts and omissions, and the precipitous
20 decline in the market value of the Company’s securities, Plaintiff and other Class members have
21 suffered significant losses and damages.
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28 ¹ All emphases included herein are added unless otherwise indicated.

JURISDICTION AND VENUE

9. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

11. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). Gritstone is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' activities took place within this Judicial District.

12. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

13. Plaintiff, as set forth in the attached Certification, acquired Gritstone securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

14. Defendant Gritstone is a Delaware corporation with principal executive offices located at 5959 Horton Street, Suite 300, Emeryville, California 94608. Gritstone's common stock trades in an efficient market on the Nasdaq Global Select Market ("NASDAQ") under the ticker symbol "GRTS".

15. Defendant Andrew R. Allen ("Allen") has served as Gritstone's President, Chief Executive Officer, and Director at all relevant times.

1 16. Defendant Vassiliki Economides (“Economides”) has served as Gritstone’s
2 Executive Vice President and Chief Financial Officer at all relevant times.

3 17. Defendants Allen and Economides are collectively referred to herein as the
4 “Individual Defendants.”

5 18. The Individual Defendants possessed the power and authority to control the
6 contents of Gritstone’s SEC filings, press releases, and other market communications. The
7 Individual Defendants were provided with copies of Gritstone’s SEC filings and press releases
8 alleged herein to be misleading prior to or shortly after their issuance and had the ability and
9 opportunity to prevent their issuance or to cause them to be corrected. Because of their positions
10 with Gritstone, and their access to material information available to them but not to the public,
11 the Individual Defendants knew that the adverse facts specified herein had not been disclosed to
12 and were being concealed from the public, and that the positive representations being made were
13 then materially false and misleading. The Individual Defendants are liable for the false statements
14 and omissions pleaded herein.
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16 19. Gritstone and the Individual Defendants are collectively referred to herein as
17 “Defendants.”
18

19 **SUBSTANTIVE ALLEGATIONS**

20 **Background**

21 20. Gritstone, a clinical-stage biotechnology company, engages in developing
22 vaccine-based immunotherapy candidates against cancer and infectious diseases.
23

24 **Materially False and Misleading Statements Issued During the Class Period**

25 21. The Class Period begins on March 9, 2023, when Gritstone filed an Annual Report
26 on Form 10-K with the SEC, reporting the Company’s financial and operational results for the
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28

1 year ended December 31, 2022 (the “2022 10-K”). In providing an overview of the Company,
2 the 2022 10-K stated, in relevant part:

3 We are a clinical-stage biotechnology company focused on combining
4 immunological insights with proprietary technologies and capabilities to develop
5 next-generation vaccines. Specifically, we discover, develop, manufacture and
6 deliver vaccine-based immunotherapy candidates against cancer and infectious
7 disease. Our goal is to unlock more potent and durable immunity by harnessing
8 vaccine innovation. We aim to achieve that goal by leveraging our in-house
9 capabilities and technologies to address the shortcomings of currently available
10 vaccines and immunotherapies.

11 The immune system sits at the nexus of many diseases and we believe that
12 immune response modulation is core to several transformational product classes.
13 Recent advances have pointed to T cells as being central to the success of cancer
14 immunotherapy and critical in the elimination of virally infected cells. We believe
15 that our scientific approach of focusing on generating antigen-specific T cells,
16 particularly the challenging but critical cytotoxic CD8+ T cell subclass has the
17 potential to drive transformational therapeutic and prophylactic benefits.

18 In oncology, we develop personalized vaccines that aim to destroy tumors
19 through CD8+ (killer) T cell recognition of tumor cells by virtue of their surface
20 display of neoantigens, peptides that are presented on cancer cells when certain
21 mutations occur in tumor DNA. We have two clinical-stage oncology programs,
22 both for common solid cancers. The first, GRANITE, focuses on development of
23 individualized vaccines based on each patient’s tumor DNA/RNA sequence (i.e.,
24 each vaccine is developed for each individual patient). The second, SLATE,
25 focuses on development of “off-the-shelf” vaccines for sets of patients that share
26 common tumor antigens including neoantigens. The scientific approaches to
27 GRANITE and SLATE are similar, and we believe the technologies we developed
28 to execute against them, i.e., to identify neoantigens accurately and deploy powerful
killer T cell-stimulating vectors to deliver them, are capable of driving more potent
and durable immune responses. In infectious disease, we develop both therapeutic
and prophylactic vaccines targeting both T cells and B cells. We believe we are
leading the field of development and application of self-amplifying mRNA
(samRNA), a rapidly-emerging platform technology. Our unique approach to
immunogen design, whereby our vaccines deliver, as appropriate, whole proteins
to drive neutralizing antibodies (nAbs) and/or protein fragments to drive T cell
responses, has the potential to both neutralize incoming pathogens (through nAbs)
and kill infected cells through CD8+ T cell recognition of foreign, pathogen-
derived peptides displayed on the surface of infected cells.

self-amplifying mRNA (samRNA)

Gritstone was the first to introduce samRNA encapsulated in lipid nanoparticles (LNP) into clinical trials in 2018. We believe that samRNA has the ability to boost pre-existing T cell responses and the potential to drive differentiated immune responses (potent and durable) in infectious disease.

Our samRNA vector is based on a synthetic RNA molecule derived from a wild-type Venezuelan Equine Encephalitis Virus (VEEV) replicon with the goal of extending the duration and magnitude of immunogen expression to drive potent and durable immune responses. Our samRNA is delivered in a LNP formulation. We are deploying this vector across our clinical stage programs. Like traditional mRNA vaccines, samRNA vaccines use the host cell's transcription system to produce target antigens to stimulate adaptive immunity. Unlike traditional mRNA, the RNA replicates once inside the cell, theoretically leading to high and durable antigen expression.

Potential benefits of samRNA may include extended duration and magnitude of antigen expression, strong and durable induction or boosting of neutralizing antibody and T cell immunity (CD8+ and CD4+), dose sparing, and a refrigerator-stable product.

22. Further, in discussing the Company's strategy, the 2022 10-K stated, in relevant part:

We believe that our team of industry leaders, each possessing specific expertise across our core disciplines of cancer genomics, immunology and vaccinology, clinical development, regulatory, and biomanufacturing, can successfully deliver groundbreaking vaccine-based immunotherapies for cancer and infectious disease by executing on the following strategic priorities:

- ***Continue deploying and optimizing our next-generation vectors to drive potent and durable immune responses suited to the clinical context.*** Chimpanzee Adenovirus 68 (ChAd) and self-amplifying mRNA (samRNA) are our two vectors of choice based on their unique and synergistic properties. In multiple studies across our oncology and infectious disease platforms, we have exhibited the ability to deploy them individually and in combination to drive potent and durable immune responses based on the clinical context. We continue to improve and optimize these proprietary vectors for their use across our programs.
- ***Continue building, automating, and optimizing our in-house biomanufacturing capabilities to increase scalability and capacity.*** We believe the speed, quality, reliability, and scalability of our manufacturing capabilities is a core competitive advantage to our clinical development and potential commercial success. We have successfully internalized all

1 biomanufacturing steps to drive down both cost and production time, as well
2 as establish full control over intellectual property and product quality. We
3 have internalized the majority of our quality control testing elements as
4 well, though we outsource where prudent and feasible. We believe that
5 operating our own manufacturing facility provides us with enhanced control
6 of material supply for both clinical trials and the commercial market, will
7 enable the more rapid implementation of process changes, and will allow
8 for better long-term manufacturing cost control. We have the capability to
9 manufacture every element involved in clinical development of our
10 oncology vaccine-based immunotherapies.

23. In addition, in discussing the Company's manufacturing, the 2022 10-K stated, in
relevant part:

10 Manufacturing is a vital component of our individualized immunotherapy
11 platform, and we are devoting significant resources to manufacturing and process
12 development in an effort to maintain the potential safety and efficacy of our product
13 candidates, as well as to reduce our per-unit manufacturing costs and time to
14 market. The production of our individualized immunotherapy candidates requires
15 two distinct elements for each patient: tumor biopsy analysis to determine candidate
16 neoantigens, followed by manufacture of vectors containing an individualized
17 cassette encoding the selected neoantigens. SLATE and CORAL contains a fixed
18 cassette with TSNA or SARS-CoV-2 vaccine constructs that is shared across cancer
19 patients/subjects rather than a cassette unique to an individual patient, which is
20 designed to provide an off-the-shelf alternative to our individualized manufactured
21 product candidate, GRANITE. The manufacture of these vectors involves complex
22 processes, including per-patient plasmid production, mammalian cell production of
23 virus and RNA synthesis and lipid encapsulation. SLATE and CORAL
24 manufacturing, as a fixed, "off-the-shelf" product candidate, are not time-sensitive
25 and while manufacturing scale differs, both are relatively straightforward
26 operationally. GRANITE, on the other hand, is an "N of 1" product candidate and
27 is manufactured in real-time for each patient, which involves a greater logistical
28 burden.

22 To achieve this, our process development group is focused on several key
23 initiatives. The first is investigating novel approaches to manufacturing our
24 products, including process optimization and quality by design of each
25 intermediate, drug substance and drug product. Additionally, we are systematically
26 characterizing our manufacturing processes, including product intermediates and
27 manufacturing unit operations. This characterization effort is designed to enable us
28 to implement process changes over the entire product lifecycle and to quickly react
to evolving process technologies that can lead to reductions in per-unit
manufacturing costs and shorter process cycle times. In addition, we plan to
establish automated, closed-platform manufacturing processes. Our goal is for
these processes to enable us to conduct manufacturing in a lower-classified, lower

1 cost manufacturing environment for multiple steps of our drug product
2 manufacturing.

3 24. In addition, in discussing the Company's CORAL Development Program, the
4 2022 10-K stated, in relevant part:

5 A pre-IND interaction with the FDA was conducted to review the proposed
6 clinical investigation of ChAd vectors encoding the SARS-CoV-2 and CD8+ T-cell
7 epitope spike antigen sequences in normal healthy subjects. The FDA concluded
8 that the overall manufacturing and release testing for the CORAL vaccines
9 candidates, which is similar to the GRANITE/SLATE process, appeared acceptable
10 and requested detail on the transfection process, grade of materials, and release tests
11 be submitted in the IND. We also received feedback that pre-clinical
12 pharmacokinetic, and toxicology studies conducted in support of the GRANITE
13 IND could be used to support the safety information needed to initiate the SARS-
14 CoV-2 clinical study, and that additional animal immune response
pharmacodynamic data would be submitted within the IND. The FDA previewed
the proposed clinical protocol, confirmed that the overall design appeared
reasonable and requested we include language to clarify dose escalation, stopping
rules and a sentinel arm. The FDA requested that we exclude those subjects who
are being treated with COVID-19 investigational agents or who have a high risk of
potential exposure to SARS-CoV-2.

15 25. Finally, in discussing the Company's employees, the 2022 10-K stated, in relevant
16 part:

17 As a mission-driven organization, we value and foster a culture of
18 collaboration, discovery and passion, which is reflected in our hiring and retention
19 strategies. We employ talented individuals who have the skills and expertise to meet
20 the challenges of our mission, and we recognize that our employees are key to our
21 success. ***Our human capital objectives include hiring goals set to provide us with
necessary expertise, integrating new employees, and retaining, incentivizing and
developing our existing employees.***

22 As of December 31, 2022, we had 233 full-time employees, including a total
23 of 54 employees with M.D. or Ph.D. degrees. Within our workforce, 100 employees
24 are engaged in research and development, 85 in manufacturing and quality, and 48
25 are engaged in business development, finance, legal, human resources, facilities,
information technology and general management and administration. None of our
employees are represented by labor unions or covered by collective bargaining
agreements. We consider our relationship with our employees to be good.

26 26. Appended to the 2022 10-K as an exhibit was a signed certification pursuant to the
27 Sarbanes-Oxley Act of 2002 by the Individual Defendants, attesting that "[t]he information
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1 contained in the Report fairly presents, in all material respects, the financial condition and results
2 of operations of the Company.”

3 27. That same day, Gritstone hosted an earnings call with investors and analysts to
4 discuss the Company’s Q4 2022 results (the “Q4 2022 Earnings Call”). During the scripted
5 portion of the Q4 2022 Earnings Call, Defendant Allen stated, in relevant part:
6

7 Gritstone was formed to pursue a big idea and take a bold approach to driving a
8 potentially transformative novel product class. Over the seven years since our
9 founding, we’ve carefully curated and advanced our set of capabilities and
10 technologies, with the aim of driving more potent and durable tumor specific
immune responses, and then infectious disease immune responses. We now sit at
the threshold of proving out our new antigen approach in metastatic colorectal
cancer and the accomplishment that could open up cold solid tumors.

11 Additionally, we’re pioneering a novel technology that could represent the next
12 RNA platform approach against infectious disease. We look forward to what will
13 be an exciting year ahead for Gritstone and to continuing to share our findings with
14 you throughout that time. And with that, I’d like to thank you all for joining us
today.

15 28. On May 11, 2023, Gritstone issued a press release announcing the Company’s Q1
16 2023 financial results. The press release quoted Defendant Allen as stating, in relevant part:

17 “Along with the significant progress in GRANITE, the data flowing from our
18 CORAL program is highly encouraging and provides early signals of the potential
19 advantages of self-amplifying mRNA (samRNA) over first-generation mRNA
20 against infectious disease. We recently observed durable neutralizing antibody
21 titers at 6 months following samRNA vaccination in over 100 vaccine-naïve
22 subjects treated within our CORAL-CEPI trial, where interim results were
23 presented at ECCMID 2023. Self-amplifying mRNA has several distinct
24 characteristics including prolonged and elevated antigen expression that suggest it
could play a key role in the induction of long-term, variant-proof immune
protection. We look forward to continuing to work with our collaborators to
demonstrate the full potential of our samRNA platform against SARS-CoV-2 and
other important viruses.”

25 29. That same day, Gritstone hosted an earnings call with investors and analysts to
26 discuss the Company’s Q1 2023 results (the “Q1 2023 Earnings Call”). During the scripted
27 portion of the Q1 2023 Earnings Call, Defendant Allen stated, in relevant part:
28

We look forward to continuing to work with collaborators to demonstrate the full potential of our samRNA platform against both SARS-CoV-2 and other important viruses. We expect to share additional data from our CORAL program this fall. And these data will relate to different immunogen designs, illustrating the flexibility of the platform to accommodate both B Cell and T cell epitopes in efficient formats. It is clear that there is still need for next generation solutions against COVID-19 and the recent actions by the White House and BARDA are encouraging signals that the pursuit of enhanced breadth and durability of protection is not going to the wayside. Outside of our PCV and SARS-CoV-2 programs, our forward looking efforts to identify and develop potentially transformative vaccines continues.

So as described today, happily Gritstone is in a period of significant momentum, robust enrollment within our PCV program, GRANITE has enabled steady expansion, and the generation of additional clinical and scientific data to inform the future development of GRANITE and further validate our approach to solid tumors. Within infectious disease, we're pioneering a novel technology that could represent the next RNA platform approach against SARS-CoV-2 and beyond. We look forward to continuing to share our findings with you as progress continues.

30. On August 9, 2023, Gritstone issued a press release announcing the Company's Q2 2023 financial results. The press release quoted Defendant Allen as stating, in relevant part:

"Additionally, the promising data we continue to see from our CORAL (SARS-CoV-2 vaccine) program highlights the differentiation and potential advantages of self-amplifying mRNA (samRNA) over current vaccines against infectious diseases. Our recent publication in Nature Communications demonstrates the scientific rigor of our work to date and the ability of our samRNA platform to drive potent and durable immune responses. We believe our samRNA vaccine candidates have demonstrated strong potential to serve as next-generation vaccine solutions to COVID-19 and other infectious diseases."

31. On September 27, 2023, Gritstone issued a press release entitled "Gritstone bio Awarded BARDA Contract to Conduct Comparative Phase 2b Study Evaluating Next-Generation Vaccine Candidate for COVID-19 Valued at up to \$433 Million." The press release stated, in relevant part:

Gritstone [. . .] announced today that it was awarded a contract by the Biomedical Advanced Research and Development Authority (BARDA) to conduct a Phase 2b comparative study evaluating Gritstone's self-amplifying mRNA (samRNA) vaccine candidate containing Spike plus other viral targets to protect against COVID-19. The agreement, which is valued at up to \$433 million, was awarded as part of 'Project NextGen,' an initiative by the U.S. Department of Health and

Human Services (HHS) to advance a pipeline of new, innovative vaccines and therapeutics providing broader and more durable protection for COVID-19.

Under the contract, Gritstone bio will conduct a 10,000 participant, randomized Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of the Gritstone next-generation COVID-19 vaccine candidate with an approved COVID-19 vaccine. ***Preparations for the study are underway, and execution of the study will be fully funded by BARDA.*** Gritstone will run the study in the United States in collaboration with the COVID-19 Prevention Network (CoVPN), a NIAID-supported network of clinical trial sites based at Fred Hutchinson Cancer Center with experience conducting large COVID-19 vaccine trials.

“We are honored to receive this award from BARDA to advance our next-generation samRNA vaccine against COVID-19 (the CORAL program), which provides strong validation of our innovative vaccine platform in infectious diseases. Not only does this contract supply the necessary resources to advance the development of CORAL, but it also signifies the trust and confidence the U.S. government has placed in our novel vaccine approach,” said [Defendant] Allen[.] “First-generation COVID-19 vaccines provided great utility during the height of the pandemic but are limited in breadth and durability of clinical protection. CORAL was designed to address these limitations by inducing durable neutralizing antibody and T cell-based immunity against current and future SARS-CoV-2 variants. Across multiple Phase 1 studies, our samRNA vaccine, which incorporates both Spike and other viral targets (Spike plus), has demonstrated induction of potent immune responses with potential to drive broad and durable clinical protection – this potential will now be tested in a randomized setting. ***We are excited about this opportunity to work alongside BARDA and look forward to initiating the Phase 2b study (CORAL-BARDA) in the first quarter of 2024.*** With CORAL moving into a randomized Phase 2 study alongside our personalized cancer vaccine program (GRANITE), Gritstone now sits at the precipice of unlocking the full potential of our novel vaccine platforms in both oncology and infectious diseases.”

32. On October 11, 2023, Gritstone issued a press release entitled “Presentations at IDWeek 2023 Highlight Potentially Differentiated Immunogenicity of Gritstone bio’s Next Generation COVID-19 Vaccine.” The press stated, in relevant part:

“The findings presented at IDWeek highlight the potential of our self-amplifying mRNA vaccine to address the limitations of today’s approved vaccines against COVID-19 and provide additional clinical rationale for our novel ‘spike-plus’ approach as we advance into a large head-to-head study,” said [Defendant] Allen[.] “These data reaffirm previous findings that our samRNA vaccines have the potential to drive highly durable antibody responses, to enhance immunity through broader T cell responses, and to accomplish this at RNA doses as low as 3 micrograms, one tenth the dose of currently approved mRNA vaccines for COVID-19. The collective data showing that elicited neutralizing antibody titers persist at

high levels for at least 12 months – data shared for the first time during IDWeek 2023 – are particularly exciting and further validate the rapid ongoing advancement of the CORAL program. ***Preparations for the BARDA-funded, 10,000 subject Phase 2b, head-to-head study are underway, having entered the base period, and we look forward to initiating the study in the first quarter of 2024.***

33. On November 8, 2023, Gritstone issued a press release announcing the Company's Q3 2023 financial results. The press release stated, in relevant part:

Infectious Disease Programs

CORAL – Next-generation SARS-CoV-2 vaccine program that serves as proof-of-concept for Gritstone's samRNA platform and novel approach in infectious diseases

- **In September 2023, Gritstone was awarded a contract by BARDA (the Biomedical Advanced Research and Development Authority), part of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services, to conduct a Phase 2b comparative study evaluating its next-generation vaccine candidate against COVID-19[.]** Per the contract, which is valued at up to \$433.0 million, Gritstone is currently preparing to conduct a 10,000 participant, randomized Phase 2b double-blinded study to compare the efficacy, safety, and immunogenicity of Gritstone's samRNA vaccine candidate against an approved COVID-19 vaccine. ***Preparations for the study are covered under the initial base period of the contract. Gritstone expects the study to be initiated in the first quarter of 2024.***

34. On February 12, 2024, Gritstone issued a press release entitled "Gritstone bio Announces Update to Comparative Phase 2b COVID-19 Clinical Trial." The press release stated, in relevant part:

Gritstone bio [. . .] today announced that it is now preparing to launch the Phase 2b head-to-head trial of its next-generation COVID-19 vaccine in the Fall of 2024 rather than 1Q24. This is to allow use of fully GMP-grade raw materials in the vaccine, which is expected to increase the regulatory utility of the trial.

"After recent communication with the FDA and input from our colleagues at BARDA, we are now making the necessary preparations to begin the Phase 2b study later this year using fully GMP-grade materials in the manufacture of our self-amplifying mRNA (samRNA) vaccine," said [Defendant] Allen[.] "The change likely increases the regulatory value of this large study, is expected to improve study interpretability, and may enable us to contemporaneously address the latest seasonal variant. We would like to thank the FDA for their collaboration and BARDA for their teamwork in support of this study, which aims to help deliver to the world a broader and more durable vaccine against COVID-19."

35. The statements referenced in ¶¶ 21-34 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) the Company would be unable to launch the Phase 2b CORAL Study in the timeframe it had represented to investors; (ii) the foregoing would impair Gritstone's ability to obtain external funding in connection with the Study, thereby negatively affecting Gritstone's ability to maintain its balance sheet and cash position; (iii) accordingly, Gritstone overstated its ability to successfully develop and commercialize its products; (iv) as a result, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

36. On February 29, 2024, Gritstone issued a press release entitled "Gritstone bio Announces Workforce Reduction." The press release stated, in relevant part:

Gritstone [. . .] today announced an approximately 40% reduction of its workforce. The move comes following the recently announced delay of the proposed CORAL Phase 2b study, which resulted in Gritstone not receiving external funding it previously anticipated beginning in 1Q 2024, associated with the initiation of the study.

"The lack of near-term funding necessitated this difficult step to fortify our balance sheet and cash position, which unfortunately means an impact to our workforce," said [Defendant] Allen[.] "I would like to express my sincere thanks to our departing employees for their contributions and reiterate our enthusiasm for the programs that they have helped build. We continue to gather GRANITE data, and remain excited about sharing our first dataset later this quarter."

Gritstone's core programs and anticipated milestones remain unchanged. Preliminary data from Phase 2 portion of Phase 2/3 study evaluating GRANITE, Gritstone's personalized cancer vaccine, in front-line metastatic, microsatellite-stable colorectal cancer (MSS-CRC), remain expected in 1Q 2024.

37. On this news, Gritstone's stock price fell \$0.78 per share, or 27.86%, to close at \$2.02 per share on March 1, 2024.

1 38. As a result of Defendants' wrongful acts and omissions, and the precipitous
2 decline in the market value of the Company's securities, Plaintiff and other Class members have
3 suffered significant losses and damages.

4 **SCIENTER ALLEGATIONS**

5 39. During the Class Period, Defendants had both the motive and opportunity to
6 commit fraud. They also had actual knowledge of the misleading nature of the statements they
7 made, or acted in reckless disregard of the true information known to them at the time. In so
8 doing, Defendants participated in a scheme to defraud and committed acts, practices, and
9 participated in a course of business that operated as a fraud or deceit on purchasers of the
10 Company's securities during the Class Period.

11 **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

12 40. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil
13 Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise
14 acquired Gritstone securities during the Class Period (the "Class"); and were damaged upon the
15 revelation of the alleged corrective disclosures. Excluded from the Class are Defendants herein,
16 the officers and directors of the Company, at all relevant times, members of their immediate
17 families and their legal representatives, heirs, successors or assigns and any entity in which
18 Defendants have or had a controlling interest.

19 41. The members of the Class are so numerous that joinder of all members is
20 impracticable. Throughout the Class Period, Gritstone securities were actively traded on the
21 NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and
22 can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds
23 or thousands of members in the proposed Class. Record owners and other members of the Class
24 may be identified from records maintained by Gritstone or its transfer agent and may be notified
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1 of the pendency of this action by mail, using the form of notice similar to that customarily used
2 in securities class actions.

3 42. Plaintiff's claims are typical of the claims of the members of the Class as all
4 members of the Class are similarly affected by Defendants' wrongful conduct in violation of
5 federal law that is complained of herein.
6

7 43. Plaintiff will fairly and adequately protect the interests of the members of the Class
8 and has retained counsel competent and experienced in class and securities litigation. Plaintiff
9 has no interests antagonistic to or in conflict with those of the Class.

10 44. Common questions of law and fact exist as to all members of the Class and
11 predominate over any questions solely affecting individual members of the Class. Among the
12 questions of law and fact common to the Class are:
13

- 14 • whether the federal securities laws were violated by Defendants' acts as alleged
15 herein;
- 16 • whether statements made by Defendants to the investing public during the Class
17 Period misrepresented material facts about the business, operations and
18 management of Gritstone;
- 19 • whether the Individual Defendants caused Gritstone to issue false and
20 misleading financial statements during the Class Period;
- 21 • whether Defendants acted knowingly or recklessly in issuing false and
22 misleading financial statements;
- 23 • whether the prices of Gritstone securities during the Class Period were
24 artificially inflated because of the Defendants' conduct complained of herein;
25 and
- 26 • whether the members of the Class have sustained damages and, if so, what is the
27 proper measure of damages.
28

45. A class action is superior to all other available methods for the fair and efficient
adjudication of this controversy since joinder of all members is impracticable. Furthermore, as
the damages suffered by individual Class members may be relatively small, the expense and

1 burden of individual litigation make it impossible for members of the Class to individually redress
2 the wrongs done to them. There will be no difficulty in the management of this action as a class
3 action.

4 46. Plaintiff will rely, in part, upon the presumption of reliance established by the
5 fraud-on-the-market doctrine in that:
6

- 7 • Defendants made public misrepresentations or failed to disclose material facts
8 during the Class Period;
- 9 • the omissions and misrepresentations were material;
- 10 • Gritstone securities are traded in an efficient market;
- 11 • the Company's shares were liquid and traded with moderate to heavy volume
12 during the Class Period;
- 13 • the Company traded on the NASDAQ and was covered by multiple analysts;
- 14 • the misrepresentations and omissions alleged would tend to induce a reasonable
15 investor to misjudge the value of the Company's securities; and
- 16 • Plaintiff and members of the Class purchased, acquired and/or sold Gritstone
17 securities between the time the Defendants failed to disclose or misrepresented
18 material facts and the time the true facts were disclosed, without knowledge of
19 the omitted or misrepresented facts.

20 47. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a
21 presumption of reliance upon the integrity of the market.

22 48. Alternatively, Plaintiff and the members of the Class are entitled to the
23 presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State*
24 *of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material
25 information in their Class Period statements in violation of a duty to disclose such information,
26 as detailed above.
27
28

COUNT I**(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)**

49. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

50. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

51. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Gritstone securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Gritstone securities and options at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

52. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Gritstone securities. Such reports, filings, releases and statements were

1 materially false and misleading in that they failed to disclose material adverse information and
2 misrepresented the truth about Gritstone's finances and business prospects.

3 53. By virtue of their positions at Gritstone, Defendants had actual knowledge of the
4 materially false and misleading statements and material omissions alleged herein and intended
5 thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants
6 acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose
7 such facts as would reveal the materially false and misleading nature of the statements made,
8 although such facts were readily available to Defendants. Said acts and omissions of Defendants
9 were committed willfully or with reckless disregard for the truth. In addition, each Defendant
10 knew or recklessly disregarded that material facts were being misrepresented or omitted as
11 described above.
12

13 54. Information showing that Defendants acted knowingly or with reckless disregard
14 for the truth is peculiarly within Defendants' knowledge and control. As the senior managers
15 and/or directors of Gritstone, the Individual Defendants had knowledge of the details of
16 Gritstone's internal affairs.
17

18 55. The Individual Defendants are liable both directly and indirectly for the wrongs
19 complained of herein. Because of their positions of control and authority, the Individual
20 Defendants were able to and did, directly or indirectly, control the content of the statements of
21 Gritstone. As officers and/or directors of a publicly-held company, the Individual Defendants
22 had a duty to disseminate timely, accurate, and truthful information with respect to Gritstone's
23 businesses, operations, future financial condition and future prospects. As a result of the
24 dissemination of the aforementioned false and misleading reports, releases and public statements,
25 the market price of Gritstone securities was artificially inflated throughout the Class Period. In
26 ignorance of the adverse facts concerning Gritstone's business and financial condition which were
27
28

1 concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise
2 acquired Gritstone securities at artificially inflated prices and relied upon the price of the
3 securities, the integrity of the market for the securities and/or upon statements disseminated by
4 Defendants, and were damaged thereby.

5
6 56. During the Class Period, Gritstone securities were traded on an active and efficient
7 market. Plaintiff and the other members of the Class, relying on the materially false and
8 misleading statements described herein, which the Defendants made, issued or caused to be
9 disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares
10 of Gritstone securities at prices artificially inflated by Defendants' wrongful conduct. Had
11 Plaintiff and the other members of the Class known the truth, they would not have purchased or
12 otherwise acquired said securities, or would not have purchased or otherwise acquired them at the
13 inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and
14 the Class, the true value of Gritstone securities was substantially lower than the prices paid by
15 Plaintiff and the other members of the Class. The market price of Gritstone securities declined
16 sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class
17 members.
18

19 57. By reason of the conduct alleged herein, Defendants knowingly or recklessly,
20 directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5
21 promulgated thereunder.
22

23 58. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and
24 the other members of the Class suffered damages in connection with their respective purchases,
25 acquisitions and sales of the Company's securities during the Class Period, upon the disclosure
26 that the Company had been disseminating misrepresented financial statements to the investing
27 public.
28

COUNT II**(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)**

59. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

60. During the Class Period, the Individual Defendants participated in the operation and management of Gritstone, and conducted and participated, directly and indirectly, in the conduct of Gritstone's business affairs. Because of their senior positions, they knew the adverse non-public information about Gritstone's misstatement of income and expenses and false financial statements.

61. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Gritstone's financial condition and results of operations, and to correct promptly any public statements issued by Gritstone which had become materially false or misleading.

62. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Gritstone disseminated in the marketplace during the Class Period concerning Gritstone's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Gritstone to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of Gritstone within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Gritstone securities.

63. Each of the Individual Defendants, therefore, acted as a controlling person of Gritstone. By reason of their senior management positions and/or being directors of Gritstone, each of the Individual Defendants had the power to direct the actions of, and exercised the same

1 to cause, Gritstone to engage in the unlawful acts and conduct complained of herein. Each of the
 2 Individual Defendants exercised control over the general operations of Gritstone and possessed
 3 the power to control the specific activities which comprise the primary violations about which
 4 Plaintiff and the other members of the Class complain.

5 64. By reason of the above conduct, the Individual Defendants are liable pursuant to
 6 Section 20(a) of the Exchange Act for the violations committed by Gritstone.
 7

8 **PRAYER FOR RELIEF**

9 **WHEREFORE**, Plaintiff demands judgment against Defendants as follows:

10 A. Determining that the instant action may be maintained as a class action under Rule
 11 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;
 12

13 B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by
 14 reason of the acts and transactions alleged herein;

15 C. Awarding Plaintiff and the other members of the Class prejudgment and post-
 16 judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

17 D. Awarding such other and further relief as this Court may deem just and proper.

18 **DEMAND FOR TRIAL BY JURY**

19 Plaintiff hereby demands a trial by jury.

20 Dated: June 17, 2024

21 Respectfully submitted,

22 POMERANTZ LLP

23 /s/ Jennifer Pafiti

24 Jennifer Pafiti (SBN 282790)

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